**AMENDMENTS TO THE CLAIMS** 

This listing of claims will replace all prior versions, and listings, of claims in the present

Docket No.: 3493-0126P

application.

**Listing of Claims:** 

1. (Currently Amended) Pharmaceutical A pharmaceutical composition comprising 5

to 20% of an idazoxan salt or of idazoxan hydrate, 10 to 40% of microcrystalline cellulose, 1 to

5% of lubricant, 0.1 to 0.5% of colloidal silica and from 29.5% to 84.8% of lactose, with respect

to the total mass.

2. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1, in which wherein the salt is the hydrochloride.

3. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form I characterized by the

X-ray diffraction spectrum presented in Figure 1.

4. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form I characterized by an

X-ray diffraction spectrum comprising characteristic peaks at approximately 4.0200, 6.6400,

Docket No.: 3493-0126P

6.9000, 7.0800, 8.0800, 9.0000, 9.9600, 9.9600, 10.8400, 11.7200, 12.1400, 12.3800, 12.9800, 13.3000, 13.5200, 14.9000, 15.0600, 15.2400 and 21.4000 degrees θ.

- 5. (Currently Amended) Pharmaceutical The pharmaceutical composition according to Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form I characterized by an X-ray diffraction spectrum comprising characteristic peaks at approximately 4.0200, 6.6400, 6.9000, 7.0800, 8.0800, 9.0000, 9.9600, 9.9600, 10.8400, 11.7200, 12.1400, 12.3800, 12.9800, 13.3000, 13.5200, 14.9000, 15.0600, 15.2400 and 21.4000 degrees θ and lacking at least one peak at approximately 4.7400, 5.7200, 8.9200, 16.8600 or 18.9000 degrees θ.
- 6. (Currently Amended) Pharmaceutical The pharmaceutical composition according to Claims 3 to 5, in which the 1 or 2, wherein said polymorph of form I is characterized by a differential thermal analysis thermogram exhibiting a single maximum value at approximately  $207.5 \pm 0.2$ .
- 7. (**Currently Amended**) Pharmaceutical The pharmaceutical composition according to Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form III characterized by the X-ray diffraction spectrum presented in Figure 3.
- 8. (Currently Amended) Pharmaceutical The pharmaceutical composition according to Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form III characterized by

an X-ray diffraction spectrum comprising characteristic peaks at approximately 4.0400, 4.7000,

Docket No.: 3493-0126P

5.7400, 6.6200, 6.9200, 7.4600, 8.0400, 8.7800, 8.9800, 9.9800, 10.8200, 11.4600, 11.6400,

12.3200, 12.9400, 13.5400, 14.2400, 15.0600, 15.6200 and 16.8400 degrees θ.

9. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claims 7 and 8, in which the claim 7, wherein said polymorph of form III is characterized by a

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $203.8 \pm 0.5$ .

10. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form IV characterized by

the X-ray diffraction spectrum presented in Figure 4.

11. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form IV characterized by

an X-ray diffraction spectrum comprising characteristic peaks at approximately 4.8000, 5.9000,

6.8400, 7.3200, 8.0800, 8.6600, 9.4600, 9.6800, 11.1600, 11.4000, 11.9000, 12.2200, 12.6800,

13.8400, 14.4200, 14.9800 and 18.1000 degrees  $\theta$ .

12. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1 or 2, in which the wherein said idazoxan is the polymorph of form IV characterized by

Docket No.: 3493-0126P

an X-ray diffraction spectrum comprising characteristic peaks at approximately 4.8000, 5.9000,

6.8400, 7.3200, 8.0800, 8.6600, 9.4600, 9.6800, 11.1600, 11.4000, 11.9000, 12.2200, 12.6800,

13.8400, 14.4200, 14.9800 and 18.1000 degrees  $\theta$  and lacking at least one peak at approximately

6.6800, 13.5400, 15.6800, 16.8600 or 18.9000 degrees  $\theta$ .

13. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claims 10 to 12, in which the Claim 10, wherein said polymorph of form IV is characterized by a

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $205.3 \pm 0.5$ .

14. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1, in which the wherein said idazoxan monohydrate is the polymorph of form V

characterized by the X-ray diffraction spectrum presented in Figure 5.

15. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claim 1, in which the wherein said idazoxan monohydrate is the polymorph of form V

characterized by an X-ray diffraction spectrum comprising characteristic peaks at approximately

5.0400, 5.8400, 7.9400, 9.2800, 9.4400, 10.1200, 12.0200, 12.5600, 12.9200, 13.7400, 13.9400,

14.5200, 14.8200, 15.2800, 16.2800 and 16.7400 degrees  $\theta$ .

**Application No. 10/722,451** 

Art Unit 1617

Reply to Office Action of November 1, 2006 (Restriction Requirement)

16. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Docket No.: 3493-0126P

Claim 1, in which the wherein said idazoxan monohydrate is the polymorph of form V

characterized by an X-ray diffraction spectrum comprising characteristic peaks at approximately

5.0400, 5.8400, 7.9400, 9.2800, 9.4400, 10.1200, 12.0200, 12.5600, 12.9200, 13.7400, 13.9400,

14.5200, 14.8200, 15.2800, 16.2800 and 16.7400 degrees  $\theta$  and lacking at least one peak at

approximately 4.7400, 6.6800, 7.5000, 8.9200, 11.5200, 14.3000, 15.6800 or 18.9000 degrees θ.

17. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claims 14 to 16, in which the wherein said idazoxan monohydrate polymorph of form V is

characterized by a differential thermal analysis thermogram exhibiting a single maximum value

at approximately  $205.6 \pm 0.4$ .

18. (Currently Amended) Pharmaceutical The pharmaceutical composition according to

Claims 1 to 17, in which claim 1 or 2, wherein the lubricant is glyceryl behenate.

19. (Currently Amended) Composition The pharmaceutical composition according to

Claims 1 to 18, which is provided claim 1 or 2, said composition is in a form suitable for oral

administration.

20. (Currently Amended) Tablets, A tablet comprising a pharmaceutical composition

according to Claims 1 to 19. Claim 1 or 2.

Docket No.: 3493-0126P

21. (Currently Amended) Tablets, A tablet according to Claim 20, characterized in that

they have wherein said tablet has a mass of between 50 and 1 000 mg, preferably between 100

and 600 mg.

22. (Currently Amended) Tablets, A tablet according to Claims 20 and 21, Claim 21,

characterized in that they are wherein said tablet is provided in a leaktight packaging.

23. (Currently Amended) Tablets, A tablet according to Claim 22, characterized in that

wherein the packaging leaktight to water vapour is composed of a tablet bottle made of

polypropylene or of high-density polyethylene, of an aluminium sachet or, and preferably, or of

an all-aluminium blister pack.

24. (Currently Amended) Process A process for the manufacture of a tablet according to

one of Claims 20 to 23, Claim 20, said process comprising a stage of direct tableting of a powder

mixture.

25. (Currently Amended) Process The process for the manufacture of a tablet according

to Claim 24, characterized in that the wherein said tableting is preceded by a stage of dry

granulation, for example by compacting.

- Docket No.: 3493-0126P
- 26. (Currently Amended) Manufacturing The manufacturing process according to Claim 25, in which wherein the active principle has a particle size, expressed by its mean
- diameter, of between 50 and 250 microns.
- 27. (Currently Amended) Manufacturing The manufacturing process according to
- Claim 25, in which wherein the active principle has a mean particle size preferably of between
- 75 and 150 microns and more particularly in the region of 100 to 125 microns.
- 28. (Currently Amended) Manufacturing The manufacturing process according to
- Claims 24 to 27, in which Claim 24, wherein the active principle has a bulk density of between
- 0.4 and <u>0.8.</u> 0.8 and preferably between 0.5 and 0.7 and more preferably still in the region of 0.6.
  - 29. (Currently Amended) Use of a composition according to Claims 1 to 19 or of a
- tablet according to Claims 20 to 23 as medicament intended for the preventive and/or curative
- treatment of A method for treating a pathology selected from the group consisting of depression,
- Parkinson's disease and severe psychotic disorders, such as schizophrenia and schizoaffective
- disorders, said method comprising administering the pharmaceutical composition of Claim 1 to a
- patient in need thereof.
- 30. (Currently Amended) Use of a composition according to Claims 1 to 19 or of a

tablet according to Claims 20 to 23, A method of treating a severe psychotic disorder, said

**Application No. 10/722,451** 

Art Unit 1617

Reply to Office Action of November 1, 2006 (Restriction Requirement)

method comprising administering the pharmaceutical composition of Claim 1 to a patient in need

Docket No.: 3493-0126P

thereof in combination with an atypical antipsychotic neuroleptic exhibiting a greater antagonist

affinity for the dopamine  $D_2$  receptor than is its antagonist affinity for the  $\alpha_2$ -adrenoreceptor, as

medicament for the preventive and/or curative treatment of severe psychotic disorders, such as

schizophrenia and schizoaffective disorders. α2-adrenoreceptor.

31. (Currently Amended) Use according to Claim 30, characterized in that The method

according to Claim 30, wherein the said atypical neuroleptic is chosen from olanzapine,

quetiapine, risperidone, sertindole or ziprasidone.

32. (Currently Amended) Polymeric A polymeric form I of idazoxan wherein the X-

Ray spectra comprises specific peaks at about 4,0200, 6,6400, 6,9000, 7,0800, 8,0800, 9,0000,

9,9600, 9,9600, 10,8400, 11,7200, 12,1400, 12,3800, 12,9800, 13,3000, 13,5200, 14,9000,

15,0600, 15,2400 and 21,4000 degrees  $\theta$ .

33. (Currently Amended) Polymeric A polymeric form I of idazoxan wherein the X-

Ray spectra comprises specific peaks at about 4,0200, 6.6400, 6.9000, 7.0800, 8.0800, 9.0000,

9.9600, 9.9600, 10.8400, 11.7200, 12.1400, 12.3800, 12.9800, 13.3000, 13.5200, 14.9000,

15.0600, 15.2400 and 21.4000 degrees  $\theta$  and lacking at least one peak at about 4.0200, 6.6400.

6.9000, 7.0800, 8.0800, 9.0000, 9.9600, 9.9600, 10.8400, 11.7200, 12.1400, 12.3800, 12.9800,

13.3000, 13.5200, 14.9000, 15.0600, 15.2400 and 21.4000 degrees  $\theta$ .

34. (Currently Amended) Polymeric A polymeric form I of idazoxan wherein the

Docket No.: 3493-0126P

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $207.5 \pm 0.2$ .

35. (Currently Amended) Polymeric A polymeric form II of idazoxan wherein the X-

Ray spectra comprises the specific peaks at about 4.7400, 5.7200, 6.6800, 7.5000, 8.9200,

9.9600, 11.5200, 12.3000, 12.9400, 13.5400, 14.3000, 15.6800, 16.8600 and 18.9000 degrees θ.

36. (Currently Amended) Polymeric A polymeric form II of idaxozan wherein the

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $203.0 \pm 0.4$ .

37. (Currently Amended) Polymeric A polymeric form III of idazoxan wherein the X-

Ray spectra comprises the specific peaks at about 4,0400, 4,7000, 5,7400, 6,6200, 6,9200.

7.4600, 8.0400, 8.7800, 8.9800, 9.9800, 10.8200, 11.4600, 11.6400, 12.3200, 12.9400, 13.5400,

14.2400, 15.0600, 15.6200 and 16.8400 degrees θ.

38. (Currently Amended) Polymeric A polymeric form III of idazoxan wherein the

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $203.8 \pm 0.5$ .

**Application No. 10/722,451** 

Art Unit 1617

Reply to Office Action of November 1, 2006 (Restriction Requirement)

39. (Currently Amended) Polymeric A polymeric form IV of idazoxan wherein the X-

Docket No.: 3493-0126P

Ray spectra comprises the specific peaks at about 4.8000, 5.9000, 6.8400, 7.3200, 8.0800,

8.6600, 9.4600, 9.6800, 11.1600, 11.4000, 11.9000, 12.2200, 12.6800, 13.8400, 14.4200,

14.9800 and 18.1000 degrees  $\theta$ .

40. (Currently Amended) Polymeric A polymeric form IV of idazoxan wherein the X-

Ray spectra comprises the specific peaks at about 4.8000, 5.9000, 6.8400, 7.3200, 8.0800,

8.6600, 9.4600, 9.6800, 11.1600, 11.4000, 11.9000, 12.2200, 12.6800, 13.8400, 14.4200,

14.9800 and 18.1000 degrees  $\theta$  and lacking at least one peak at about 6.6800, 13.5400, 15.6800,

16.8600 or 18.9000 degrees θ.

41. (Currently Amended) Polymeric A polymeric form IV of idazoxan wherein the

differential thermal analysis thermogram exhibiting a single maximum value at approximately

 $205.3 \pm 0.5$ .

42. (Currently Amended) Polymeric A polymeric form V of idazoxan wherein the X-

Ray spectra comprises the specific peaks at about 5.0400, 5.8400, 7.9400, 9.2800, 9.4400,

10.1200, 12.0200, 12.5600, 12.9200, 13.7400, 13.9400, 14.5200, 14.8200, 15.2800, 16.2800 and

16.7400 degrees  $\theta$ .

Reply to Office Action of November 1, 2006 (Restriction Requirement)

43. (Currently Amended) Polymeric A polymeric form V of idazoxan wherein the X-Ray spectra comprises the specific peaks at about 5.0400, 5.8400, 7.9400, 9.2800, 9.4400, 10.1200, 12.0200, 12.5600, 12.9200, 13.7400, 13.9400, 14.5200, 14.8200, 15.2800, 16.2800 and 16.7400 degrees  $\theta$  and lacking at least one peak at about 4.7400, 6.6800, 7.5000, 8.9200, 11.5200, 14.3000, 15.6800 or 18.9000 degrees  $\theta$ .

Docket No.: 3493-0126P